

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	10/029,294	VOGEL ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08 December 2005.
2. ☒ The allowed claim(s) is/are 1-4, 8-10, 12-16 and 19-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

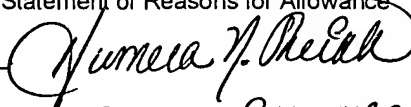
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 12/28/01 are accepted by the Examiner.

**Attachment(s)**

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|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
|---|---|

  
 PATENT EXAMINER  
 TC 1600

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Amendment after Final Office Action (under 37 C.F.R. §1.116), Applicant's Arguments/Remarks and the request for extension of time (1 month-granted), all filed 12/08/05 is acknowledged.

Claims 1-4, 8-10, 12-16 and 19-23 are pending in this action. Claims 1, 9, 13, 14, 19 and 20 have been amended. New claims 21-23 have been added. Claims 5-7, 11, 17 and 18 have been cancelled. Claims 1-4, 8-10, 12-16 and 19-23 are allowed.

### ***Specification***

The title of the application has been changed to "IMPLANTABLE PARTICLES FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE".

## **EXAMINER'S AMENDMENT**

The application has been amended as follows:

### **In the Specification:**

On page 1, in the 'Cross-Reference to Related Applications' section, line 7, after the term 'reference', the phrase "**, and claims benefit of 60/077,166 filed March 06, 1998**" has been added.

In the Claims:

In claim 19, section (a), last line, the phrase 'about 1 to about 30%' has been changed to 'about 1% to about 30%'.

The following claims have been renumbered and/or the claim dependencies have been changed to be in proper dependent form:

Claims 8, 9 and 10 have been renumbered as claims 5, 6 and 7.

Claims 12, 13, 14, 15 and 16 have been renumbered as claims 8, 9, 10, 11 and 12.

Claim 19 has been renumbered as claim 13.

Claim 22 has been renumbered as claim 14 and now depends upon claim 13 (originally filed claim 19).

Claim 20 has been renumbered as claim 15 and now depends upon claim 14 (originally filed claim 22).

Claim 21 has been renumbered as claim 16 and now depends upon claim 15.

Claim 23 has been renumbered as claim 17 and now depends upon claim 14 (originally filed claim 22).

***Allowable Subject Matter***

Claims 1-4, 8-10, 12-16 and 19-23 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Rajagopalan *et al.* U.S. Pat. No. 5,843,987 & Boschetti *et al.* U.S. Pat. No. 5,635,215) does not disclose nor fairly suggest or teach the instantly claimed method for treating gastroesophageal reflux disease comprising implanting a tissue-bulking amount of microparticles into the lower esophageal sphincter or diaphragm. The prior art further fails to disclose or teach a method for treating gastroesophageal reflux disease comprising implanting a tissue-bulking amount of microparticles into the lower esophageal sphincter or diaphragm, whereby the microparticles comprise a biocompatible, non-toxic, hydrophilic copolymer comprising in copolymerized form (a) about 25% to about 99% by weight of neutral hydrophilic acrylic monomer, (b) about 2% to about 30% by weight of one or more monomers having a cationic charge and (c) about 1% to about 30% by weight of a functionalized monomer. In contrast, the prior art (Rajagopalan *et al.* '987) teaches a method of treating gastroesophageal reflux disease (GERD) by administering a biologically active drug (ellagic acid; a plant phenol), wherein the drug affects gastrointestinal (GI) motility. The '987 reference does not teach implanting a tissue-bulking amount of microparticles into the lower esophageal sphincter or diaphragm. The '987 reference is also silent as to the implantation of microparticles having components (a)-(c) delineated above. The secondary reference (Boschetti *et al.* '215) is also lacking and does not satisfy the deficiencies of Rajagopalan *et al.* '987, in that the Boschetti '215 reference does not teach microparticles for the treatment of GERD, nor any method of tissue-bulking.

The instant invention demonstrates an improvement over prior art methods because it provides for less invasive and more permanent effects on the patient compared to surgery.

In the telephonic interview dated 11/23/05 held between applicant's representative and myself, suggestions were made to incorporate the limitations of claim 11 into claim 1; to replace the term 'administering' in claim 1 with 'implanting'; and to incorporate the term 'non-toxic' between the terms 'biocompatible' and 'hydrophilic copolymer'. Applicant's representative adopted the suggestions made by the Examiner and have amended the claims, placing the instant application in condition for allowance. Thus, in view of the amendment and lack of the instantly claimed method for treating GERD by the prior art, the instant application is rendered patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

January 19, 2006

  
TC-1600